



BILLING CODE 6560-50-P

ENVIRONMENTAL PROTECTION AGENCY

[EPA-HQ-OPP-2015-0713; FRL-9948-78-OEI]

Agency Information Collection Activities; Submitted to OMB for Review and Approval; Comment Request; Submission of Protocols and Study Reports for Environmental Research Involving Human Subjects

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: EPA has submitted the following information collection request (ICR) to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act (PRA): “Submission of Protocols and Study Reports for Environmental Research Involving Human Subjects” (EPA ICR No. 2195.05, OMB Control No. 2070-0169). This is a request to renew the approval of an existing ICR, which is currently approved through August 31, 2016. EPA did not receive any comments in response to the previously provided public review opportunity issued in the **Federal Register** of December 24, 2015 (80 FR 80360). With this submission, EPA is providing an additional 30 days for public review.

DATES: Comments must be received on or before *[insert date 30 days after date of publication in the **Federal Register**]*.

ADDRESSES: Submit your comments, identified by docket identification (ID) number EPA-HQ-OPP-2015-0713, to both EPA and OMB as follows:

- To EPA online using <http://www.regulations.gov> (our preferred method) or by mail to: EPA Docket Center, Environmental Protection Agency, Mail Code 28221T, 1200 Pennsylvania Ave., NW., Washington, DC 20460.

- To OMB via email to oir_submission@omb.eop.gov. Address comments to OMB Desk Officer for EPA.

EPA's policy is that all comments received will be included in the docket without change, including any personal information provided, unless the comment includes profanity, threats, information claimed to be Confidential Business Information (CBI), or other information for which disclosure is restricted by statute. Do not submit electronically any information you consider to be CBI or other information for which disclosure is restricted by statute.

FOR FURTHER INFORMATION CONTACT: Ramé Cromwell, Field and External Affairs Division (7605P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number: (703) 308-9068; email address: cromwell.rame@epa.gov.

SUPPLEMENTARY INFORMATION:

Docket: Supporting documents, including the ICR that explains in detail the information collection activities and the related burden and cost estimates that are summarized in this document, are available in the docket for this ICR. The docket can be viewed online at <http://www.regulations.gov> or in person at the EPA Docket Center, West William Jefferson Clinton Bldg., Rm. 3334, 1301 Constitution Ave., NW., Washington, DC. The telephone number for the Docket Center is (202) 566-1744. For additional information about EPA's public docket, visit <http://www.epa.gov/dockets>.

ICR status: This ICR is currently scheduled to expire on August 31, 2016. Under OMB regulations, the Agency may continue to conduct or sponsor the collection of information while this submission is pending at OMB.

Under the PRA, 44 U.S.C. 3501 *et seq.*, an agency may not conduct or sponsor, and a person is not required to respond to, a collection of information, unless it displays a currently valid OMB control number. The OMB control numbers are displayed either by publication in the **Federal Register** or by other appropriate means, such as on the related collection instrument or form, if applicable. The display of OMB control numbers for certain EPA regulations is consolidated in 40 CFR part 9.

Abstract: EPA is responsible for the regulation of pesticides under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) and the Federal Food, Drug, and Cosmetic Act (FFDCA). As revised in 2006 and 2013, EPA regulations at 40 CFR Part 26 protect the subjects of “third-party” human research (i.e., research that is not conducted or supported by EPA). In addition to other protections, the regulations require affected entities to submit information to EPA and an institutional review board (IRB) prior to initiating, and to EPA upon the completion of, certain studies that involve human research participants. The information collection activity consists of activity-driven reporting and recordkeeping requirements for those who intend to conduct research for submission to EPA under the pesticide laws. If such research involves intentional dosing of human subjects, these individuals (respondents) are required to submit study protocols to EPA and a cognizant local Human Subjects IRB before such research is initiated so that the scientific design and ethical standards that will be employed during the proposed study may be reviewed and approved. Also, respondents are required to submit information about the ethical conduct of completed research that involved human subjects when such research is submitted to EPA.

Respondents/Affected Entities: Entities potentially affected by this ICR are any entities that submits protocols and study reports for environmental research involving human

subjects under FIFRA and/or FFDCA.

Respondent's obligation to respond: Mandatory (40 CFR Part 26).

Estimated total number of potential respondents: 7 annually for research involving intentional exposure of human subjects and 10 annually for all other submitted research with human subjects.

Frequency of response: On occasion.

Estimated total burden: 10,242 hours (per year). Burden is defined at 5 CFR 1320.3(b).

Estimated total costs: \$ 923,121 (per year), includes \$0 annualized capital investment or maintenance and operational costs.

Changes in the estimates: There is a decrease of 4,711 hours in the total estimated respondent burden compared with that identified in the ICR currently approved by OMB. This decrease is due to a reduction in the preparation of protocols and studies. This change is an adjustment.

Authority: 44 U.S.C. 3501 *et seq.*

Courtney Kerwin, Director, Regulatory Support Division

[FR Doc. 2016-20605 Filed: 8/26/2016 8:45 am; Publication Date: 8/29/2016]